



Fw: NEWS UPDATES: EPA Faces Industry-Backed Challenge To Libby Asbestos Risk Assessment (Risk Policy Report)

Carol Campbell

to:

10/13/2011 10:40 AM

Cc:

"Judy Hansen"

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From: Carol Campbell/R8/USEPA/US

To:

Cc: "Judy Hansen" <Hansen.Judy@epamail.epa.gov>

Libby - Risk Assessment

Pls print

From: "Rodriguez-Newstrom, Linda" [Rodriguez-NewstromL@cdm.com]

Sent: 10/13/2011 11:58 AM AST

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Subject: FW: NEWS UPDATES: EPA Faces Industry-Backed Challenge To Libby Asbestos Risk Assessment (Risk Policy Report)

Fyl...

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Sent: Thursday, October 13, 2011 9:50 AM

To: Rodriguez-Newstrom, Linda

Subject: Fw: NEWS UPDATES: EPA Faces Industry-Backed Challenge To Libby Asbestos Risk Assessment (Risk Policy Report)

FYI Report on the IRIS Listening session

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From: Maureen Gwinn/DC/USEPA/US

Date: 10/13/2011 09:41AM

Subject: Fw: NEWS UPDATES: EPA Faces Industry-Backed Challenge To Libby Asbestos Risk Assessment (Risk Policy Report)

I apologize if you've already seen this...

EPA Faces Industry-Backed Challenge To Libby Asbestos Risk Assessment

Posted: October 7, 2011

A consultant for W.R. Grace & Co., the company that mined asbestos in Libby, MT, is challenging EPA's draft risk assessment for the particular form of the carcinogenic substance that originates in that area, claiming the analysis is based upon outdated, simplistic models and "inappropriately" selected data – an important challenge as the risk analysis could lead to costly cleanup regulations.

At issue is EPA's draft risk assessment for Libby amphibole (LA) asbestos, a substance present in insulation in homes throughout the country and one that is believed responsible for widespread illness and death in the Montana town where it was mined. The agency released the draft for public comment Aug. 25, after previewing key details of the assessment in May. In the coming months, the draft assessment will be peer-reviewed by EPA's Science Advisory Board. The agency is accepting public comment on the draft through Oct. 24.

W.R. Grace & Co. retained Suresh Moolgavkar, of the consulting firm Exponent, Inc., to critique the draft assessment. During an Oct. 6 listening session EPA hosted in Arlington, VA, Moolgavkar challenged several aspects of the draft document in a presentation to EPA staff, largely related to the data and models used in the assessment. *Relevant documents are available on InsideEPA.com. (Doc ID: 2378290)*

For example, Moolgavkar argues that both the cancer and non-cancer risk estimates in the draft assessment of LA are "based on severely and inappropriately restricted data sets." He notes several incidents where EPA uses a subset of epidemiological data from Libby workers, with which he disagrees. He adds that EPA "discards most of the data" from the epidemiological study

of workers used to calculate the draft noncancer risk estimate. According to Moolgavkar's presentation, EPA "restricts [its] analyses to workers with 'good' exposure data (57 cases [of localized pleural thickening, an alteration to the sack that surrounds the lung] among 250 participants reduced to 12 among 119 participants)."

Similarly, he notes that in EPA's analysis of mesothelioma risk -- a deadly lung cancer caused by asbestos exposure -- "jettisoning the full Libby data set in favor of a smaller data set because the full data do not find a significant effect of concentration . . . is unwarranted." Moolgavkar also criticized the model the agency uses for assessing mesothelioma risk as "a giant step backwards because it ignores the important role played by pattern of exposure, rather than just cumulative exposure, in determining risk."

EPA's lung cancer model "should have been extended to examine the role of pattern of exposure, rather than just cumulative exposure," Moolgavkar says. He notes that the lung cancer model debuted in 1972 to analyze clinical trial data, which rarely last more than a few years, as opposed to often decades-long epidemiological studies of exposed workers used in risk assessments like that of LA.

Moolgavkar said it is clear "that considerable time and effort has been devoted to" preparing the draft risk assessment, but nonetheless said the report, "is unevenly written and certain chapters omit critical information."

EPA's draft risk assessment for LA is already under fire from White House and Defense Department (DOD) officials, who are urging the agency to include less-stringent cancer models in the document. According to comments DOD and the White House Office of Management & Budget (OMB) previously submitted to the EPA, the agency "should present both linear and nonlinear low-dose modeling for the observed cancer effects of" LA.

Linear versus nonlinear modeling is a long-standing issue in agency risk assessments, in part due to EPA's guidance on how its risk assessors should conduct cancer risk assessments. The document instructs EPA to perform the modeling dependent on how the chemical is biologically understood to cause cancer. If there is insufficient information to determine the mode of action (MOA), or how the chemical causes cancer, then the more health-protective linear modeling is used. This modeling assumes that there is no safe level of exposure to the chemical under assessment. Similarly, EPA uses linear modeling for chemicals with a mutagenic MOA. This type of stringent risk modeling is often opposed by those who would have to pay for cleanups or other mitigations based on such assessments.

But, if the MOA is known and not mutagenic, nonlinear modeling can be used. This modeling assumes that there is some amount of the chemical below which exposure will not cause harm. This usually results in less strict assessments, which are often supported by industry or other federal agencies that could be responsible for mitigating the chemical's effects.

So far, EPA has conducted only linear cancer modeling for LA because it has determined that it is unknown how LA causes cancer (*Risk Policy Report*, Aug. 30).

For cancer effects from inhalation of asbestos, EPA in the draft assessment proposes establishing an inhalation unit risk (IUR), or estimate of inhaled cancer potency, of 0.17 fibers per cubic centimeter (f/cc)-1. By doing so, EPA continues to suggest that LA is somewhat less toxic than the generic mix of asbestos fibers the agency typically assumes when making cleanup decisions, despite concerns from activists that LA is more toxic. The agency's established IUR for the generic mix is 0.23 (f/cc)-1.

EPA proposed a noncancer reference concentration (RfC) -- the amount of asbestos EPA considers an individual could breathe daily over a lifetime without effect -- of 0.00002 (f/cc). The figure is below 0.00005, which activists say represents a typical, naturally occurring background level of asbestos. Suggesting an RfC below background "is a frightening statement about how toxic Libby amphiboles are," one activist said previously.

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